



CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid’s Quality System, in compliance with the US Food and Drug Administration’s Quality System Requirements, ISO 13485, European IVD Directive and the Canadian Medical Device Regulations (CMDR). .

Product Name: Xpert® vanA

Cepheid Catalogue Part No.: GXVANA-10

Kit Lot No.: 1001465388

Cartridge Lot No.: 08001

Kit Expiration Date: 2025-12-14

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA



Solna



Sunnyvale



Lodi

Functional Testing according to D16902, Rev. U

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	vanA Positive	Passed
Negative	vanA Negative	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

Molly Doan
Molly Doan (Dec 29, 2024 10:34 PST)

Dec 29, 2024

Signature of Quality Assurance

Date

Name: Molly Doan

Title: Quality Systems Specialist





301-6218 Rev B_ C of A GXVANA

Final Audit Report

2024-12-29

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